

REMARKS

Claims 1-13 are pending in the instant application. Claims 1-13 have been rejected by the Examiner.

By the above amendments Claims 2, 4 and 5 has been canceled without prejudice; Claims 1, 3 and 6-13 have been amended to more particularly point out and distinctly claim the subject matter which Applicants regard as the invention; and new Claim 14 has been added to present claims of varying scope. More particularly, Claim 1 has been amended to recite that the moisture sensitive active ingredient is topiramate, support for which amendment may be found in, for example page 4, lines 9-11 of the specification as filed, and further in dependent Claim 2 as originally filed. Further, Claims 1, 3 and 6-12 have been amended to specify that the phases are cylindrical layers, support for which amendment may be found in for example, page 7, lines 5-8 of the specification as originally filed. Additionally, Claims 12 and 13 have been amended to remove the "if desired" clauses rejected by the Examiner as indefinite under 35 U.S.C. §112, second paragraph. Finally, new Claim 14 has been added, support for which may be found in for example, page 7, lines 26-29 of the specification as filed, and further in Claim 8 as originally filed. Applicants submit that the amendments are fully supported by the specification as filed, and no new matter is being added.

After entry of the amendments, Claims 1, 3 and 6-14 will remain pending and under consideration. Reconsideration of the captioned application based on the previous amendments and following remarks is respectfully requested.

The Examiner has rejected Claims 1-13 under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description requirement. More particularly, the Examiner states that the specification does not support a genus of moisture sensitive active ingredients, beyond the single example of topiramate.

Without conceding the correctness of the rejection, and solely to advance the prosecution of instant application, Applicants have amended Claim 1 to recite that the moisture sensitive active ingredient is topiramate, thereby rendering the rejection moot.

Thus, Applicants respectfully request that the rejection of Claims 1-13 under 35 U.S.C. §112, first paragraph be withdrawn.

The Examiner has rejected Claims 12-13 under 35 U.S.C. §112, second paragraph as allegedly indefinite for the phrase "if ...desired". Applicants respectfully refer the Examiner to the above amendments of Claims 12 and 13 which remove the "if desired" clauses in Claims 12 and 13, rendering the rejection moot. Applicants therefore respectfully request that the rejection of Claims 12-13 under §112, second paragraph be withdrawn.

The Examiner has rejected Claims 1-5, 8 and 11 under 35 U.S.C. §102(b) as allegedly anticipated by PCT Publication WO 99/44581. More particularly, the Examiner states that WO'581 discloses

bi-phasic tablets comprising an effective amount of topiramate, present in a core phase, and wherein the core is coated with a phase comprising povidone (a hygroscopic gum material).... The (pre-shaped) core phase and (pre-shaped) coating phase is then compressed in an appropriate compressing apparatus. (citations omitted)

Applicants respectfully traverse the rejection and submit that the disclosure of Thakur et al., in WO 99/44851, does not anticipate the subject matter of the present invention. Applicants submit that the claims, as currently amended, are directed to bi- or multi-phasic tablets comprising the moisture sensitive active ingredient topiramate, wherein (a) the phases are cylindrical layers, (b) the topiramate is present in one or more phases, (c) at least one phase comprises a hygroscopic gum and wherein (d) none of the phases comprise both the moisture sensitive active ingredient topiramate and the hygroscopic gum. Thakur et al, in WO99/44581, disclose core particles containing an active ingredient of topiramate wherein the core particles are coated with a taste mask coating and wherein the coated particles are formulated into a sprinkle formulation or chewable tablet for patients who cannot swallow tablets. Applicants submit that the

coating described in Thakur et al., which surrounds the core particles (granules) comprising topiramate, does not correspond to a cylindrical layer as is required by amended Claim 1. Applicants maintain that as such, Thakur et al., in WO 99/44851, do not anticipate the instant invention which claims bi- or multi-phasic tablets wherein the phases are cylindrical layers. Applicants therefore respectfully request that the Examiner withdraw the rejection of Claims 1-5, 8 and 11 under § 102(b).

The Examiner has rejected Claims 1-6, 8 and 11-12 under 35 U.S.C. §103(a) as allegedly obvious in view of PCT Publication WO 99/44581. More particularly, the Examiner states that

WO'581 discloses bi-phasic tablets comprising an effective amount of topiramate, present in a core phase, and wherein the core is coated with a phase comprising povidone (a hygroscopic gum material). ... In addition, the reference teaches using alginic acid (alginate) as a substitute for povidone in the coating phase. The core phase may be compressed prior to adding the coating phase....

WO'851 fails to disclose a specific combination or example with a core phase comprising alginate. WO'851 further fails to disclose a specific example wherein the core phase is compressed prior to the coating phase. (citations omitted)

The Examiner concludes that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention as made to choose alginate as a component in the core phase"... and "[i]t would be further obvious to compress the core phase before adding the coating phase, as this is a disclosed embodiment of the invention".

Applicants respectfully traverse the rejection. Applicants respectfully refer the Examiner to the above amendments which amend Claim 1 to require that the phases are cylindrical layers. Applicants submit that as discussed above, Thakur et al., in WO 99/44851, do not teach or suggest bi- or multi-phasic tablets, but rather, disclose core particles containing an active ingredient of topiramate wherein the core particles are coated with a taste mask coating and wherein the coated particles are formulated into a sprinkle formulation or chewable tablet for patients who cannot swallow tablets. Applicants further submit that the coating described in Thakur et al., which surrounds the core

particles (granules) comprising topiramate, does not correspond to a cylindrical layer as is required by amended Claim 1. Thus, Thakur et al, in WO99/44851, do not teach or suggest the preparation of tablets comprising two or more cylindrical layers wherein at least one layer comprises topiramate and wherein none of the layers comprises both topiramate and the hygroscopic gum material. Applicants maintain that as such, Thakur et al., in WO 99/44851, do not render obvious the instant invention which claims bi- or multi-phasic tablets wherein the phases are cylindrical layers. Applicants therefore respectfully request that the Examiner withdraw the rejection of Claims 1-6, 8 and 11-12 under §103(a) based on WO 99/44851.

The Examiner has rejected Claims 1-13 under 35 U.S.C. §103(a) as allegedly obvious in view of US2005/0158385. More particularly, the Examiner states that US2005/0158385

discloses multi-layered tablets comprising three layers, namely, a core, a middle layer, and an outershell, wherein an effective amount of a pharmaceutically active compound is present in any one of the three layers, and a thermoplastic polymer may be present in any one of the three layers, and the pharmaceutical active compound and thermoplastic polymer may be in different layers.... The outershell of '385 corresponds to the coating as disclosed in Instant Claims 9-10. An exemplified pharmaceutically active compound is ...topiramate.... Preferred thermoplastic polymers include hydroxypropyl methylcellulose and xanthan gum. The core is compressed before adding the other layers with a single screw extruder. The multi-layered tablets are compressed by using an embedded cutting roll.

'385 fails to disclose a specific combination or example of a multi-layered tablet comprising topiramate and xanthan gum.

It would be obvious to one of ordinary skill in the art at the time the invention was made to prepare a multi-layered tablet comprising topiramate and xanthan gum wherein the two compounds are not in the same layer with a reasonable expectation of success ... (citations omitted)

Applicants respectfully traverse the rejection. Applicants respectfully submit that the present invention is directed to a bi- or multi-phasic tablet comprising the moisture sensitive active ingredient topiramate, wherein the phases are cylindrical layers, wherein

the topiramate is present in one or more layers, wherein at least one layer comprises a hygroscopic gum and wherein none of the layers comprise both the moisture sensitive active ingredient topiramate and the hygroscopic gum. Verreck et al., in US2005/0158385, disclose tablets comprising a core, an overlayer and a shell, wherein the overlayer and shell are applied as a coating surrounding the core (see for example, Figure 2; paragraphs [0010], [0019], [0092] of Example 1, [0095] of Example 2 and [0099] of Example 3). Thus, Verreck et al. do not teach or suggested the cylindrical layers of the present invention.

Additionally, Applicants submit that Verreck et al., in US2005/0158385, do not teach or suggest the desirability of separating the hygroscopic gum material from the moisture sensitive active ingredient as is required in the present invention. Rather, Verreck et al. teach that the overlay and / or core (either of which may contain the pharmaceutically active agent) may further contain other components, including polymers, waxes, oils, fats, surfactants and other excipients, including for example, alginic acid, gummi arabicum, xantham gummi and others (see paragraphs [0020]-[0021] and [0023]). Thus, Verreck et al., in US2005/0158385, teach that both the pharmaceutically active agent and the hygroscopic gum material may in fact be present in either the core or overlayer in contrast to the claimed invention which requires that none of the phases (cylindrical layers) contain both the moisture sensitive active ingredient topiramate and the hygroscopic gum material.

Finally, with respect to the process as in Claims 11-13, Applicants submit that the present invention is directed to a process for the preparation of the tablets as in Claim 1, comprising the compression of two or more pre-shaped (cylindrical) layers. Verreck et al., in US2005/0158385, do not teach or disclose the compression of pre-shaped layers, but rather teach the simultaneous coating of a pre-shaped core. Thus, Applicants submit that Verreck et al., in US2005/0158385, do not teach, suggest or render obvious the process of the present invention for the preparation of the bi- or multi-phasic tablets (wherein the phases are cylindrical layers).

Since the teachings in Verreck et al., US2005/0158385, would not suggest or motivate one skilled in the art to make the bi- or multi-phasic tablets of the present invention, wherein the phases are cylindrical layers and wherein none of the layers contains both the moisture sensitive active ingredient (topiramate) and the hygroscopic gum material, Applicants respectfully request that the Examiner withdraw the rejection of Claims 1-13 under §103(a) based on US2005/0158385.

In view of the above amendments and remarks, Applicants maintain that the application is in condition for allowance and passage to issue is earnestly requested.

Respectfully submitted,

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Dated: September 26, 2008